FEB 1 5 2002

K014173

510(k) Summary
SYNCHRON® Systems Salicylate Reagent

1.0 **Submitted By:**

Mary Beth Tang
Regulatory Affairs Specialist
Beckman Coulter, Inc.
200 S. Kraemer Blvd., W-104
Brea, California 92822-8000
Telephone: (714) 961-3777
Fax: (714) 961-4123

2.0 **Date Submitted:**

December 19, 2001

3.0 **Device Name(s):**

3.1 **Proprietary Names**

SYNCHRON® Systems Salicylate Reagent

3.2 **Classification Name**

Salicylate test system (21 CFR § 862.3830)
Clinical toxicology calibrator (21 CFR § 862.3200)

4.0 **Predicate Device(s):**

Beckman Coulter	Predicate	Manufacturer	Docket Number
SYNCHRON® Systems Salicylate (SALY) Reagent	TDx® Salicylate Assay	Abbott Laboratories, Inc.*	K844070

*Abbott Laboratories, Inc., Abbott Park, IL

5.0 **Description:**

The SYNCHRON System Salicylate (SALY) Reagent is designed for optimal performance on the SYNCHRON CX and LX Systems. The assay is intended for use in the quantitative determination of salicylate concentration in serum or plasma by a colorimetric timed-endpoint method. The reagent kit contains two 45-test cartridges and is packaged with the single-level calibrator.

6.0 **Intended Use:**

Salicylate (SALY) Reagent, when used in conjunction with the SYNCHRON Systems Salicylate Calibrator, is intended for the quantitative determination of salicylate concentration in serum or plasma on SYNCHRON Systems.

K014193

7.0 **Comparison to Predicate(s):**

Assay	Aspect/Characteristic	Comments
SIMILARITIES		
SYNCHRON® Systems SALY Reagent	Intended use	Same as predicate
	Sample Type	
	Liquid-stable reagents and calibrators	
	Storage conditions (+2°C to +8°C)	
DIFFERENCES		
	Methodology	**SYNCHRON**: Enzymatic, colorimetric **TDx**: Fluorescence Polarization Immunoassay (FPIA)
	Formulation	Specific to methodology
	Reportable Range	**SYNCHRON**: 4.0 – 100 mg/dL **TDx**: 0.0 – 80 mg/dL
	Sensitivity	**SYNCHRON**: 4.0 mg/dL **TDx**: 0.5 mg/dL
	Sample Size	**SYNCHRON**: 4 µL **TDx**: 3 µL

8.0 **Summary of Performance Data:**

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to chemistry test systems already in commercial distribution. Equivalence is demonstrated through method comparison and imprecision experiments that relate results obtained from the SYNCHRON Salicylate Reagent to the Abbott TDx Salicylate assay.

Method Comparison Study Results*

Analyte	N	Slope	Intercept	r	Predicate Method
SYNCHRON Salicylate Assay	75	1.096	-0.14	0.989	Abbott TDx Salicylate Assay

*Serum patient specimens were analyzed in the range of 5.1 to 95.2 mg/dL salicylate. Data shown was collected using SYNCHRON LX Systems. Equivalency between SYNCHRON CX has been established by correlation analysis to SYNCHRON LX Systems.

Estimated SYNCHRON LX Salicylate Assay Imprecision

Sample	Mean (mg/dL)	S.D. (mg/dL)	%C.V.	N
Within-Run Imprecision				
Level 1	9.7	0.36	3.8	80
Level 2	31.7	0.63	2.0	80
Level 3	82.7	0.83	1.0	80
Total Imprecision				
Level 1	9.7	0.65	6.7	80
Level 2	31.7	0.86	2.7	80
Level 3	82.7	1.93	2.3	80

The Summary of Safety and Effectiveness information for the SYNCHRON Systems Salicylate Reagent is found in TAB 1 of this notice and are being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and implementing regulation 21 CFR 807.92.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 1 5 2002

Ms. Mary Beth Tang
Regulatory Affairs Specialist
Beckman Coulter, Inc.
200 S. Kraemer Blvd.
M/S W-104
Box 8000
Brea, CA 92822-8000

Re: k014173
Trade/Device Name: SYNCHRON® Systems Salicylate Reagent
Regulation Number: 21 CFR 862.3830; 21 CFR 862.1150
Regulation Name: Salicylate test system; Calibrator
Regulatory Class: Class II; Class II
Product Code: DKJ; JIS
Dated: December 19, 2001
Received: December 20, 2001

Dear Ms. Tang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K014173

510(k) Number (if known): Not yet assigned

Device Name: **SYNCHRON® Systems Salicylate Reagent**

Indications for Use:

Salicylate (SALY) Reagent, when used in conjunction with SYNCHRON® Systems Salicylate Calibrator, is intended for the quantitative determination of salicylate in serum and plasma on Beckman Coulter's SYNCHRON Systems by a colorimetric timed-endpoint method. Measurements obtained by this device are used in diagnosis and treatment of salicylate overdose and in monitoring salicylate levels to ensure appropriate therapy.

(Division Sign-Off)
Division of Clinical
510(k) Number K014173

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use _____
(per 21 CFR 801.109) Optional Format 1-2-96